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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,098	04/16/2004	Ma. Teresa Y. Tan	DIZ-5	9265

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EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,098	TAN ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2005 and 29 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are pending in the application as of the response received on September 29, 2005.

The objection to claim 9 as being of improper multiple dependent form is withdrawn in view of the amendment of the claim.

Applicant's arguments with respect to the patentability of claims 1-14 over U.S. Patent No. 4,897,270 to Deutsch et al, U.S. Patent No. 6,080,426 to Amey et al, and U.S. Patent No.6,482,432 to Xiping Wang have been considered but are moot in view of the new ground(s) of rejection.

Priority

It is noted that Applicants have not filed a certified copy of the Philippines 12003000285 application as required by 35 U.S.C. 119(b), and thus the requirements for claiming foreign priority to PHILIPPINES 12003000285 06/06/2003, have not been satisfied. Applicant's statements that efforts are being made to retrieve this certified copy are acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the specification as originally filed does not provide support for a capsule having a rupture time of more than 40 seconds, as recited in claim 1. The specification discloses that prior art film-coated tablets rupture in less than 40 seconds (see paragraph 0007, in particular), and discloses that the rupture time of the instant capsules can be "in excess of 60 seconds" (see paragraph 0013, in particular), but does not specifically disclose that the instantly claimed capsules have rupture times of greater than 40 seconds. Appropriate correction and/or clarification is required. Claims 2-16 are rejected as being dependent upon the rejected claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, for reciting the parenthetical term "caplet." The presence of this term in parenthesis renders the claim in definite because the scope of the claim cannot be adequately determined, as the parenthetical statement represents a narrower limitation recited with the broader limitation of the more general "tablet in the shape of a capsule" as is also recited in the claim. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims recites the broad recitation that the tablet is in the shape of a capsule, which is not necessarily a caplet, and the claim also recites a caplet, which is the narrower statement of the range/limitation. Appropriate correction and/or clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 and 15-16 are rejected under 35 U.S.C. 103(a) as being obvious over WO 02/43707 to Khan et al, published June 6, 2002, in view of U.S. Patent No. 6,080,426 to Amey et al, issued June 27, 2000.

Khan et al. teaches an oral pharmaceutical form of cerufoxime axetil where the drug is contained in a tablet core and is coated with a double layered film coat (see abstract, in particular.) Khan et al. teaches that the first film coat masks the bitter taste of the cefuroxime axetil while the second film coat delays the rupture time beyond 40 seconds (see abstract, in particular.) Khan et al. teaches that the delayed rupture time is desirable because patients find it easier to swallow dosage forms that have a longer rupture time (see paragraph bridging pages 3-4, in particular.)

Regarding claims 6-8, Khan et al. furthermore teaches that the tablet can contain from 2 to 15% by weight of disintegrant, and that an effective amount of disintegrant can

be provided to achieve the desired disintegration of the tablet (preferably within 1 minute) after rupture of the film (see page 5, fourth full paragraph, in particular.)

Regarding claims 9 and 15-16, Khan et al. teaches that the disintegrant can be starch, sodium starch glycolate, croscarmellose sodium and others (see page 5, fourth full paragraph, in particular.) Regarding claim 10, Khan et al. teaches that the cefuroxime axetil is desirably in the amorphous form (see page 1, third full paragraph, in particular.)

Khan et al. does not teach providing the specific % weight ranges of disintegrant in the caplet as recited in claims 6-8. However, Khan et al. teaches providing a range of disintegrant that is overlaps with the range recited in claim 6, and that is very close to the ranges recited in claims 7-8, with the range recited in claim 7 having a lower limit (20%) that is only 5% greater than the preferred upper limit (15%) specified by Khan et al. Khan et al. furthermore teaches of the desirability of providing an effective amount of disintegrant in the tablet to disintegrate the tablet rapidly upon rupture of the film coating. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to optimize the % weight of disintegrant included in the tablet to provide the desired rate of disintegration of the tablet. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Khan et al. does not specifically teach providing the tablet in a capsule or the composition of the capsule.

Amey et al. teaches that the encapsulation of caplets in a capsule can be performed to provide a dosage form that is more easily swallowable than uncoated caplets (see column 1, lines 15-28, in particular) and that does not exhibit the disadvantageous associated with coated caplet forms, such as non-uniformity of the coating (see column 1, lines 28-50, in particular.) Thus, Amey et al. teaches that encapsulated capsule forms can be provided as an improved alternative to coated or non-coated capsules.

Regarding claims 3-5, Amey et al. teaches a process for encapsulation of caplets in a capsule comprising providing empty capsule parts, filling at least one of said capsule parts with one or more caplets, putting said capsule parts together, and treating the combined parts by cold shrinking (see abstract, in particular.) Amey et al. teaches that a specifically preferred version has a clearance of the capsule shell and caplet in the range of from about 0 to about -0.5 mm, meaning that the caplet is compressed in the capsule (see column 2, lines 50-54, in particular.) Thus, as Amey et al. teaches a caplet and capsule have less than zero clearance between each other, it follows that the diameter of the caplet taught by Amey et al. must be greater than or equal to 80% of the internal diameter of the capsule taught by Amey et al.

Regarding claims 11-12 and 14, Amey et al. teaches that suitable materials for the capsule can include gelatin, hydroxypropyl methylcellulose or starch (a polysaccharide) (see column 3, lines 18-34, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have been motivated to substitute at least one of the film coats of the greater than 40 second rupture time cerufoxime axetil tablet composition of Khan et al, with a surrounding capsule as taught by Amey et al, because Amey et al. teaches that encapsulation of caplets and tablets can advantageously be performed instead of coating such tablets, and thus teaches the interchangeability of the methods. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to provide the capsule of Amey et al. in place of at least one of the film coats of Khan et al., with the expectation of providing a suitable form for the delayed rupture and release of cerufoxime axetil.

Claims 13-14 are rejected under 35 U.S.C. 103(a) as being obvious over WO 02/43707 to Khan et al, published June 6, 2002, in view of U.S. Patent No. 6,080,426 to Amey et al, issued June 27, 2000, as applied to claims 1-12 and 15-16 above, and further in view of U.S. Patent No. 6,482,432 to Xiping Wang, issued November 19, 2002.

Khan et al. and Amey et al. are applied as discussed above, and teach providing a cefuroxime axetil tablet inside a capsule that ruptures in greater than 40 seconds. Khan et al. and Amey et al. do not specifically teach that the capsule is made of vegetable or plant-based cellulose.

Wang teaches that there is consumer demand for capsules made from vegetable sources, such as vegetable gelatin or hydroxypropyl methylcellulose (see column 1, lines 52-60, in particular.) Wang also provides examples of therapeutic ingredients being encapsulated in cellulose derivative capsules or vegetable cellulose capsules (see column 2, lines 55-61, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have been motivated to provide a capsule made of vegetable based cellulose in the encapsulated caplet dosage form of Khan et al. and Amey et al, with the expectation of providing a capsule that is suitable for encapsulating therapeutic ingredients and that is in demand by consumers.

Response to Amendment

Applicant's arguments with respect to claims 1-14 have been considered. In particular, Applicant's arguments for the patentability of the claims over U.S. Patent No. 4,897,270 to Deutsch et al. and U.S. Patent No. 6,080,426 to Amey et al. are

considered persuasive in view of Applicant's amendment to recite the capsule "having a rupture time of more than forty seconds," as in claim 1, as Deutsch et al. specifically teaches that the rupture time is less than 40 seconds. However, Applicant's arguments are moot in view of the new ground(s) of rejection discussed above that have been necessitated by Applicant's amendments to the claims.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent Application Publication No. 2003/0104048 to Patel et al. discloses a shell encapsulating a drug material, such as a soft capsule shell, that can be modified to have a desired dissolution and/or disintegration profile (see abstract and paragraphs 0033-0038, in particular). WO 99/44614 to Chung et al. discloses a cefuroxime axetil composition stabilized with an anti-gelling agent (see abstract, in particular.)

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 8:30-5:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER